



## Development of Off-the-shelf Stent Grafts for Juxtarenal Abdominal Aortic Aneurysms

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### WHAT THIS PAPER ADDS

- This report outlines the initial use of a modified fenestrated stent graft for treating juxtarenal aortic aneurysms. The device modifications might allow for a large proportion of juxtarenal aneurysms to be treated with a limited number of stent graft designs creating a pathway towards off-the-shelf design.

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### ABSTRACT

**Introduction:** The use of EVAR for more complex aneurysm anatomy has become more widespread over the past decade. Fenestrated and branched stent grafts for the visceral and iliac segment show promising short- and midterm outcome and these procedures have become routine in many vascular centers. However, at present, such grafts are customized to the individual patient and planning and manufacturing leads to significant treatment delay subjecting the patients to the risk of rupture during the waiting period. The purpose of this report is to describe the first experience in treating juxta/suprarenal aneurysms using the first version of a new fenestrated stent graft

**Material and Methods:** A fenestrated device was designed with two renal fenestrations, an SMA fenestration and a scallop for the coeliac artery. The renal arteries were designed with an inner 6 mm fenestration and an outer 15 mm diameter creating a dome to allow renal artery catheterization for a range of renal artery distribution. Seven patients with complex visceral artery anatomy were treated with customized stent grafts containing these pivot renal fenestrations.

**Results:** Technical success was uniform with 100% target vessel catheterization and 0% 30-day mortality. In one case, the graft was displaced slightly during delivery resulting in a renal artery stent occlusion at 2 months postoperatively.

**Conclusions:** The development of a modified fenestrated device has shown this to be feasible and it has the potential to reduce the need for extensive preoperative graft customization and establishing a true off the shelf platform for juxta- and suprarenal AAA.

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Endovascular aneurysm repair (EVAR) is an established treatment option for infrarenal aortic aneurysms. The results from randomised trials show that EVAR is beneficial compared to open aneurysm repair with regards to short- and midterm morbidity and mortality.<sup>1,2</sup> However, many patients are not anatomically suitable for EVAR mainly due to inadequate proximal landing and fixation zones.<sup>3</sup> This becomes even more significant in patients presenting

with aneurysm rupture where the anatomy is generally more adverse to EVAR.<sup>4</sup> Despite this, infrarenal EVAR is offered to an increasing number of patients who do not fulfil the anatomic requirements, as it is perceived as less traumatic. Recent studies raise serious concerns regarding the midterm outcome of infrarenal EVAR when applying it to patients outside of morphologic instruction for use (IFU) criteria.<sup>5</sup> Aneurysm growth during midterm follow-up is frequent in this group of patients.

The use of EVAR for more complex aneurysm anatomy has become more widespread over the past decade. Fenestrated and branched stent grafts (SGs) for the visceral segment show

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promising short- and midterm outcome and these procedures have become routine in many vascular centres.<sup>6,7</sup> However, at present, such grafts are customised to the individual patient, and planning and manufacturing leads to significant treatment delay subjecting the patients to the risk of rupture during the waiting period. The current technology is therefore not available in the acute setting.<sup>8</sup>

Alterations to fenestration as well as delivery system design might theoretically allow more patients to be treated with a few standard SG designs.

The purpose of this report is to describe the first experience in treating juxta/suprarenal aneurysms using the first version of a new fenestrated SG based on the current COOK Zenith Fenestrated device containing fenestration and delivery system modifications.

## Methods

### *The device*

The platform used in this series is based on the Zenith Fenestrated Stent graft that has been described in detail previously.<sup>7</sup> In short, the system is composed of three modular components: one proximal tubular SG bearing the fenestrations, one bifurcated component and one iliac extension limb. Fenestrations come in three configurations: small (6/8 × 6 mm) without crossing stent struts, large (8–12 mm diameter) and scallops (6–12 mm deep). Fenestrations are reinforced with a nitinol ring and marked with gold markers. The configuration of fenestrations and their positioning in height and on the circumference is planned according to individual patient anatomy based on preoperative computed tomography (CT) measurements.

To remove the need for individual case planning and thus achieve a standard design of the fenestrated proximal component, some device modifications have been introduced. In the current series, due to regulatory concerns, all SGs were tailored to specific patient anatomy and not produced in an off-the-shelf configuration. This was to allow for testing of the fenestration as well as delivery system modifications before continuing with use of a standard off-the-shelf SG. The current device is not computer tomographic angiography (CTA) marked and was delivered as a custom-made option. All cases were approved by the Departmental Review Committee.

### *Fenestration design and positioning*

To accommodate variability between the renal fenestrations and target vessel (TV) position, the renal fenestrations were modified to create a dome appearance (Fig. 1a) where the outer diameter is 15 mm and the inner diameter is 6 mm. These 'pivot fenestrations' have nitinol wire reinforcements in inner rings, outer rings and in the dome itself. This configuration theoretically allows for catheterisation of renal arteries that fall within the outer 15 mm diameter while keeping the inner 6 mm fenestration for mating stent seal. In a bench model, catheterisation of an off-clock TV through this dome fenestration allowed the mating stent to act as a pivot on deployment, directing the inner fenestration and mating stent towards the TV (Fig. 1b). This theoretically alleviates the strain on the mating stent to SG junction that occurs if a mating stent is placed through a standard fenestration into a TV that is off-position. Based on the renal and superior mesenteric artery (SMA) positions in approximately 350 patients (unpublished data), it was calculated that nearly 80% of TVs could fit into two fenestrated graft designs where the diameter of the fenestrations for the renal arteries was 15 mm (Fig. 2). The position of the SMA fenestration (8 mm diameter) was left constant at 12 o'clock and approximately 10 mm from the bottom of the coeliac scallop.

In the modified design, the renal fenestrations have been fitted with a preloaded wire to obviate the need for catheterisation of the fenestrations during the procedure. In addition, the preloaded wires run through the SG on the delivery side using a modified delivery handle which can accommodate two 6 French introducers alongside it. The original concept and design of preloaded fenestration has been previously described and reported.<sup>9</sup> In this original design, a separate preloaded wire was used for each renal fenestration. The wires were loaded through the fenestrations and into the top cap. This design was abandoned due to concerns that these wires could get trapped in the top cap and make delivery impossible. In the modified design, a single 0.018-inch, 3.5-m-long preloaded wire is used. This wire passes through the side port on the delivery handle, through the main body of the graft, out through one renal fenestration, across the graft, into the other renal fenestration, through the main body of the graft and finally out through the second side port on the delivery handle (Fig. 3). Two 6 French sheaths can thus be loaded over the wire in each side port and advanced into the renal fenestrations.

### *Top cap alteration*

In the standard fenestrated SG, the bare top stent is held in a top cap identical to that used in the Zenith Flex AAA Stent graft. After SG delivery this cap is captured and retrieved with the pusher in the delivery system. In the modified device, a 'self-retrieving' top cap has been designed. By designing a tapered tip in reversed fashion on the proximal portion of the cannula, the top cap is given a tapered profile upon deployment of the bare fixation stent. The cap can then be retrieved through the system without having to pass the pusher across the fenestrated component of the SG as is necessary with the current device. The design of the bare top stent remains identical to that of the standard fenestrated SG.

### *Spiral constraining wire*

To provide better stability and torquability of the graft after sheath removal, the inner cannula of the graft was attached to the posterior wall of the SG along its entire length. This also keeps the cannula from possibly obstructing the sheaths for the renal arteries as these are passed into position.

### *Constraining ties*

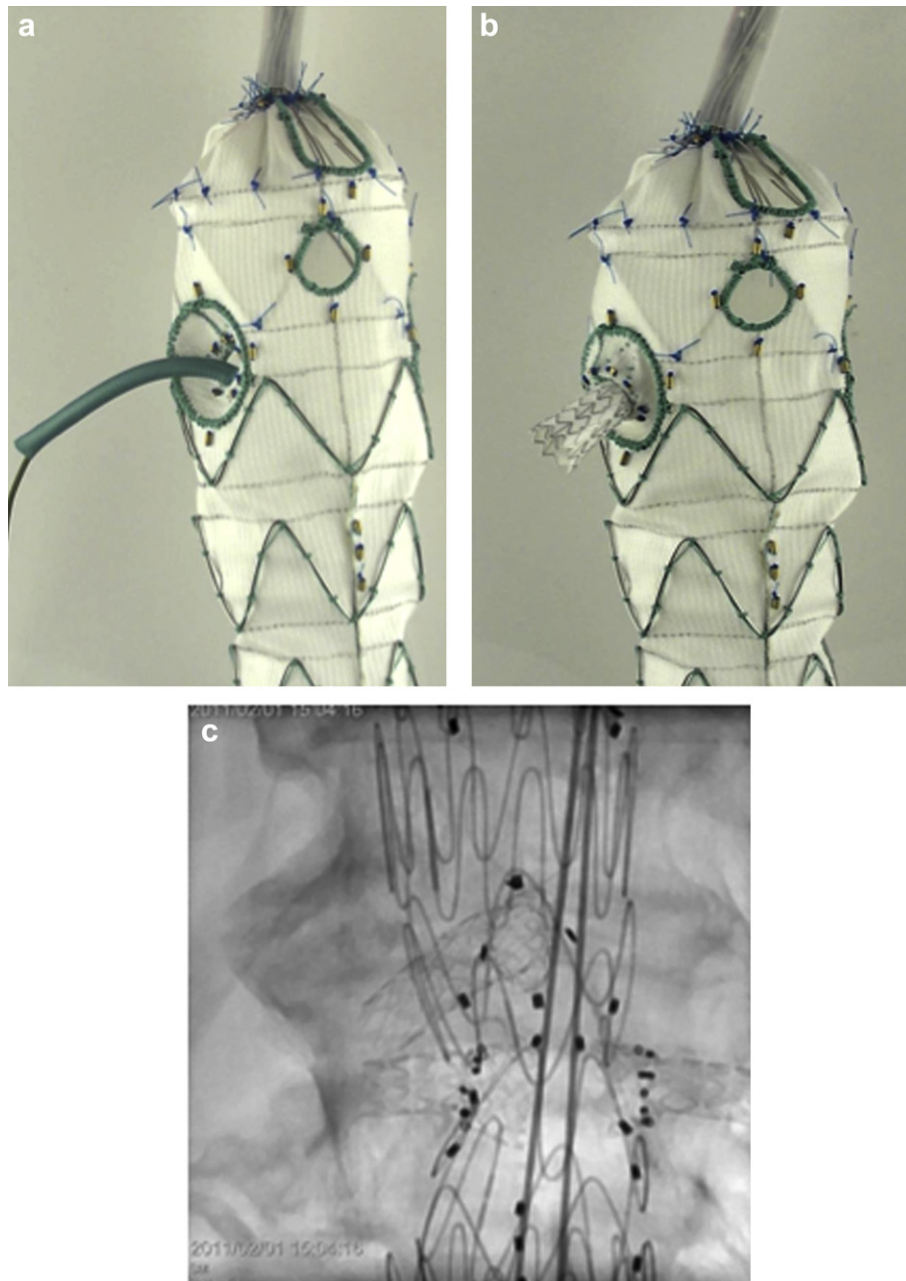
To provide increased ability to reposition the graft upon deployment, the SG incorporates double diameter reducing ties. The standard fenestrated SG only includes single diameter reducing ties.

### *Delivery sequence*

The device is oriented and positioned outside the patient under fluoroscopy as per standard fenestrated endografting.

Two 6F Flexor sheaths (COOK Inc) are introduced over the preloaded wire and positioned in the main delivery sheath. After endograft positioning in the aorta, the delivery sheath is withdrawn and the renal sheaths (Flexor 6F 90 cm, COOK Inc) are positioned in the renal fenestrations. A 12 F sheath is placed through the contralateral groin to accommodate for a diagnostic catheter as well as an SMA sheath (7F Flexor sheath 90 cm long). The SMA is then catheterised, the 7F sheath advanced and a mating covered stent positioned within the sheath.

For the renal arteries, a second puncture is then made in the 6F sheath. A 4 F Curly-Q catheter is then used with a guidewire to catheterise the renal artery. After position is confirmed, the



**Figure 1.** a Prototype of an off-the-shelf device with pivot fenestrations. The latter is seen as a dome with a catheter through the fenestration. Note the inner fenestrations, which measures 6 mm, and the outer fenestration, measuring 15 mm. Anterior on the graft is a  $8 \times 8$  mm reinforced fenestration for the superior mesenteric artery and cranial to this a 12 mm deep scallop for the coeliac trunk. b In this bench model, the deployed mating covered stent directs the pivot fenestration caudally. c Intraoperative image after stent graft deployment. Note that the left renal pivot fenestration has everted towards the renal artery (eight markers mark the inner 6 mm fenestration). On the right side, the pivot fenestration has simply flattened against the aortic wall.

glidewire is exchanged for a stiff wire (Jindo, Cordis, [www.cordis.com](http://www.cordis.com) or Rosen [www.cookmedical.com](http://www.cookmedical.com)) in the renal artery. This procedure is repeated for the second renal artery. The preloaded wire is then removed from the system so the 6F sheaths can be advanced into the renal arteries. Within the sheaths, appropriate mating covered stents are then positioned. The spiral constraining wire, diameter reducing ties and proximal trigger wire are then removed in sequence. The self-retaining top cap is then deployed. Finally, the distal trigger wire of the device, which is attached to the self-retrieving top cap, is removed positioning the top cap within the main body of the graft.

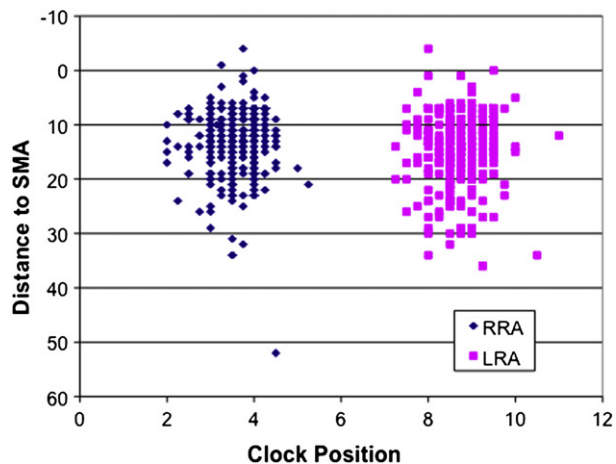
The SMA mating SG is then deployed. A CODA balloon is used over the SMA wire to mould the fenestrated sealing segment while

the renal sheaths are still in place. The renal SGs are then deployed and flared. After selective angiograms are done to confirm TV patency and integrity, the renal sheaths and wires are removed allowing the removal of the top cap.

The remainder of the procedure with placement of the distal bifurcated component and iliac extensions is done in a standard fashion.

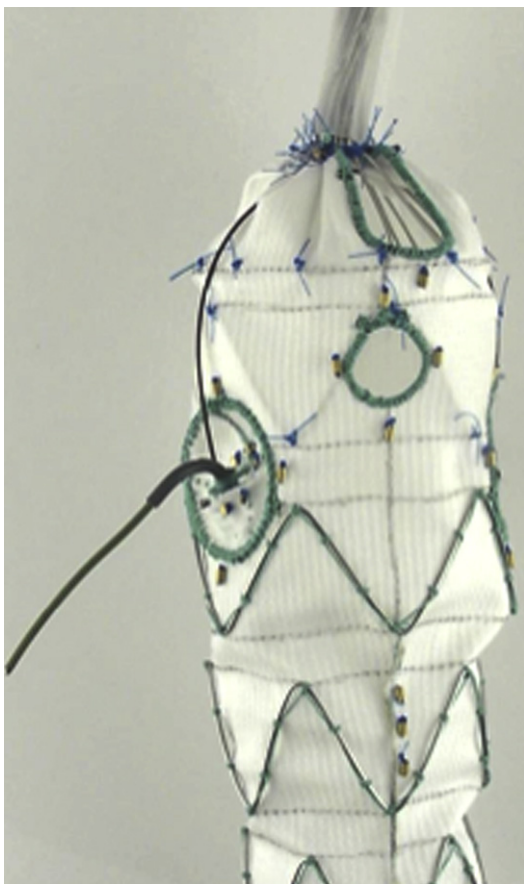
#### Patients

From Janto May 2011, seven patients (four women, mean age 72 years (range 61–80)) were treated for juxta- and suprarenal aneurysm at two major vascular centres with large EVAR experience.



**Figure 2.** Distribution of renal arteries in relationship to the superior mesenteric artery in 350 patients undergoing elective fenestrated endografting. Image courtesy of Stephan Haulon and Roy Greenberg (Cleveland Clinic Foundation, USA).

Mean aneurysm size was 60 mm (range 52–65 mm). No patient had an infrarenal neck and the aneurysm extended to the level of the renal arteries in four (juxtarenal) and between the renal arteries and SMA in three (suprarenal aneurysm). Preoperative creatinine was median  $80 \mu\text{mol l}^{-1}$  (range  $63\text{--}167 \mu\text{mol l}^{-1}$ ). Patient co-morbidities are summarised in Table 1.



**Figure 3.** Prototype device with renal pivot fenestration. Note the wire running through the fenestration cranially and back into the graft. This is the preloaded wire over which the renal sheaths are tracked.

**Table 1**  
Patient co-morbidities.

	n
Coronary heart disease	3
Hypertension	7
Smoking	7
COPD	2
Previous abdominal Surgery	4
Diabetes	0

All patients were treated with fenestrated SGs with the device modifications described above. Six out of seven devices had two renal dome fenestrations, a strut-free 8-mm standard fenestration for the SMA and a 12-mm-deep scallop for the coeliac artery. One device had two renal dome fenestrations and a scallop for the SMA (20 mm deep 10 mm wide). All procedures were completed with a bifurcated distal SG and iliac limb extension as per standard fenestrated endografting. In the current series, due to regulatory concerns, all SGs were tailored to specific patient anatomy and not produced in an off-the-shelf configuration. This was to allow for testing of the fenestration as well as delivery system modifications before continuing with use of a standard off-the-shelf SG.

## Results

All procedures were successful and the 30-day mortality was 0%. Median pre-discharge creatinine was  $88 \mu\text{mol l}^{-1}$  (range  $59\text{--}143 \mu\text{mol l}^{-1}$ ) with no patient displaying an increase over 30%. All fenestrations were catheterised successfully and mating stents placed accordingly for a perioperative TV patency of 100%. The mean operative time was 246 min (range 200–335 min) with a mean fluoro time of 69 min (29–100 min) yielding a mean radiation exposure of 35 mGy (range 8–86 mGy). The mean contrast dose was 39 g I (range 24–62.6 g I).

In 10/14 renal fenestrations, Atrium Advanta  $6 \times 22$  mm covered stents (Atrium Europe, [www.atriummed.com](http://www.atriummed.com)) were used as mating stents. In four of the pivot fenestrations, the dome did not completely evert during deployment and sheath advancement. This resulted in a longer fenestration to renal artery bridging distance. In these cases, 28-mm-long, covered stents (JoStentgraft medium, [www.abbott.com](http://www.abbott.com)) were mounted on standard percutaneous transluminal angioplasty (PTA) balloons to adequately bridge the gap. Advanta 8–38 mm covered stents were used as mating stents for the SMA.

In case number 6, there were difficulties removing the pre-loaded wire after renal artery catheterisation. This patient has a quite tortuous sealing zone in the juxtarenal aorta. Due to the friction upon wire removal, the SG migrated distally approximately 1.5 cm despite applying significant push on the delivery system. The graft also rotated about  $20^\circ$  during this manoeuvre. This resulted in the need of longer mating stents for the TV.

In case number 7, there were difficulties removing the top cap after complete system deployment, as the delivery cannula was lying very close to one side of the graft. Attempts to remove the cannula and top cap resulted in catching of one of the proximal struts of the uncovered stent. The issue was resolved by pushing on the entire sheath delivery, thereby creating a bow in the cannula making move away from its position. While applying this pushing force, the top cap could be removed.

No patient went to the intensive care unit (ICU). One patient was reoperated for femoral artery occlusion after fascial closure. This resulted in leg ischaemia and need for lower limb fasciotomy that resulted in a prolonged hospital stay (17 days). No patient displayed a significant rise in S-creatinine postoperatively.

Mean hospital stay was 8 (4–17 days) days.

## FU

All patients had CTA at 1 month. No endoleaks were detected. All TVs were patent at 1-month follow up (FU) (Fig. 4). No significant configurational changes of the bridging covered stents were seen except in patient number 6 described above.

Pat # 2 presented at 2 months post op with chest and back pain. CTA revealed a well-excluded AAA with no signs of endoleak. Three centimetres above the top of the suprarenal fixation stent of the SG, a localised dissection was seen in the descending thoracic aorta over a distance of 2 cm. The patient was treated conservatively with pain measurement and blood pressure control and symptoms disappeared over the course of 3 days. CTA after 3 days and 1 month showed unchanged appearance of the dissection as well as the treated aneurysm.

Pat # 6 presented 2 months postoperatively with slight abdominal pain and discomfort. Workup revealed an S-creatinine of  $130 \text{ mmol l}^{-1}$  compared to  $63 \text{ mmol l}^{-1}$  immediately postoperatively ( $56 \text{ mmol l}^{-1}$  preoperatively). CTA showed occlusion of the left renal stent with no flow in the left kidney that had decreased in size significantly since the preoperative scan. In addition, slight compression of the SMA stent was seen. Under local anaesthesia, both the SMA and right renal mating stents were reinforced with additional balloon expandable stents (VisiPro, [www.ev3.net](http://www.ev3.net) (8–27 mm in SMA and 7–27 mm in right renal artery)). Recanalisation of the occluded left renal stent failed. The creatinine stabilised at  $120 \text{ mmol l}^{-1}$ . On repeat CTA 6 weeks later, both SMA and the right renal mating stent were patent. Creatinine was  $120 \text{ mmol l}^{-1}$  and patient was doing well.

## Discussion

Anderson and coworkers first described EVAR for pararenal and suprarenal aneurysm with fenestrated SGs in 1999.<sup>10</sup> It has since become a valid treatment option for complex aneurysms unsuitable for standard infrarenal endografting due to the lack of adequate infrarenal sealing zone. Over 5000 implants have been performed around the world and the current COOK Zenith Fenestrated device is CE marked in Europe and undergoing clinical trials to achieve FDA approval in the US. The results from the published series show



**Figure 4.** CTA 6 weeks postoperatively showing patent renal and SMA stents and an excluded aneurysm.

a 30-day mortality of 1–5.5% and a TV patency at 1 year of 95–97%.<sup>11</sup>

The current device has some drawbacks pertaining to planning and manufacturing. Each SG has to be planned and customised to each individual patient to ensure adequate positioning of the TV fenestrations. In patients with favourable anatomy, the planning is a fairly straightforward process where the position of the fenestrations with regard to the TVs is predictable. However, in patients with more adverse anatomy the planning becomes more difficult.<sup>8,12</sup> Angulations in the juxtarenal sealing zone makes the prediction of how the graft will actually position intraoperatively more difficult. This is also true in patients where the iliac access is tortuous. The rotational movement of the graft upon introduction through the access vessels can make the final position in the sealing region incorrect. In most cases, the SG can be manually rotated to compensate for this, but in cases of extreme tortuosity and iliac narrowing, the rotational ability of the graft can be quite difficult. The combination of sealing zone angulation and access difficulties has an additive effect making fenestration placement even more unpredictable. In these situations, the fenestration can end up 'off-clock' which can lead to problems with TV catheterisation. The incorporation of additional diameter reducing sutures along the device has at times been used to increase the rotational ability when such situations are predicted. In most cases, as the data from the published literature show, TV catheterisation and mating stent placement are successful even in these more difficult situations. Concerns exist, however, that these bridging stents are subjected to additional stress and strain during follow-up when they are forced to traverse the fenestration to TV in a slightly tangential fashion.<sup>13</sup> No detailed analysis of this specific issue exists at this time.

Another aspect of the current device is the production time. The manufacturing process of these individualised grafts is time and labour consuming which lead to device delivery times of 6–8 weeks under normal circumstances. This makes the device unavailable in the emergency setting for patients presenting with symptomatic or ruptured aneurysms that lack infrarenal sealing zones. In addition, many surgeons feel hesitant to subject patients with large, asymptomatic aneurysm to a 6–8-week treatment delay while waiting for an SG.

The concept of the preloaded fenestrated SG with pivot fenestrations is a step to overcome some of these issues.<sup>14</sup> The configuration of the renal dome fenestrations in combination with a standard SMA fenestration theoretically allows 80% of TV to be within reach of the dome fenestrations using only two standardised configurations of the fenestrated cuff.<sup>15</sup> Using a standard as opposed to a customised design might also result in more offset fenestration versus renal artery position perhaps subjecting mating stents to higher stress and strain despite the dome design of the fenestration perhaps causing long term TV occlusions. Future studies of a true off-the-shelf design must study this closely. In the current series, patients were treated with customised grafts using pivot fenestrations since the anatomy in these patients (particularly neck angulation) was seen as complex and the wider 'reach' of the pivot fenestrations might be beneficial. In addition, regulatory issues prohibited us from using a standard 'off-the-shelf' design. The dome of the fenestration gives the mating stent extra space and avoids them being crushed between the graft and the aortic wall when the inner fenestration and TV are not in alignment, a situation more likely to occur in tortuous neck anatomy. If there is space between the graft and the aortic wall, the dome fenestration will actually evert during mating stent placement creating a directional cuff towards the renal artery. In this series where grafts were planned with fenestrations in alignment, the inner fenestration in most cases simply flattened against the aortic wall. On a few occasions, the dome fenestration remained inverted necessitating

the use of a longer bridging SG. If the dome remains inverted, the inner portions of the renal mating stents can come very close to each other. Although this was not an issue in the cases performed, it must be taken into consideration particularly when using the device in narrow sealing zones.

Other features of the modified graft have also been added to simplify the procedure. The addition of a spiral wire wrapping the delivery cannula to the posterior aspect of the SG provides additional rotational ability to the system once it is unsheathed. In addition, it also positions the cannula away from the fenestrations themselves so it does not interfere with cannulation of the fenestrations and TV. We have noted the increased rotational ability to be very useful in the cases performed.

The fact that the renal fenestrations have a preloaded wire running alongside the main delivery system also offers several advantages. First, it obviates the use of a large sheath in the contralateral femoral artery during the TV catheterisation phase of the procedure. Instead, an 8–12 F sheath is placed in the contralateral groin to allow catheterisation of the SMA fenestration. This allows continuous flow to the contralateral lower limb for the majority of the procedure as well as flow in the contralateral internal iliac artery that can provide some collateral flow to the ipsilateral lower limb where the femoral artery is largely occluded by the main delivery sheath. This is an important aspect, particularly during long procedures, where reperfusion injury with compartment syndrome can be a problem after flow is restored at the end of the case.<sup>16</sup>

The fourth feature of the preloaded system is the through-and-through preloaded fenestration wire. Apart from making catheterisation of the renal fenestrations themselves unnecessary, potentially making these procedures shorter, they also provide another feature. By pulling on both ends of this wire during TV catheterisation, the top end of the graft is effectively collapsed creating extra space between the graft and the aortic wall. This makes additional rotation and positioning of the graft easier if needed and also alleviates TV catheterisation particularly if the renal arteries are offset to the fenestrations. Indeed, this feature has proved to be very useful in a number of cases where we have implanted standard fenestrated grafts that have only had the preloaded wire without the pivot fenestrations themselves. In one of the cases in the current series, there was some difficulty removing the preloaded wire that resulted in graft displacement. The anatomy in this case was quite challenging with a significantly angulated sealing zone that might have contributed to this incident. This obviously raises concerns, and further testing and refinement of the device is needed to determine the root cause of this and avoiding it in the future.

Several manufacturers are in the process of developing fenestrated devices for juxtarenal aneurysms based on their corresponding infrarenal SG platform. Both the Anaconda (Vascutec) and Endologix (Ventana) SGs have been used, and reports of the first human implants have been reported at vascular conferences. The exact configuration of these devices, the level of customisation required and the degree of standardisation possible are unknown. The current design is based on the COOK Zenith Fenestrated platform. There is now over 10 years of experience with this device, and the short and midterm outcomes with regard to device delivery and durability are excellent. Although the new device described has some added features, the immediate implant success is good and

has the potential to simplify safe delivery of the graft. Additional FU will determine the durability of the new pivot fenestrations as well as TV patency.

In conclusion, the development of a modified fenestrated device has shown this to be feasible and it has the potential to reduce the need for extensive preoperative graft customisation making and establishing a true off-the-shelf platform for juxta- and suprarenal AAA.

### Conflict of Interest

TR is a consultant with COOK Medical Inc.  
SH is a consultant with COOK Medical Inc.  
BR is an employee with COOK Medical Inc.

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None declared.

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